OCT 30 2013

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
Address:	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
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Date of Summary:	April 17, 2013
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	U2 Total Knee System – PSA Type, Offset Stem Adapter
Common Name:	Semi-constrained total knee prostheses
Device Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	JWH
Predicate Device:	1. "UNITED" U2 Total Knee System – PSA Type (K082424) 2. "BIOMET" Vanguard™ 360 Revision Knee System (K093293) 3. "MEDACTA" GMK® Total Knee System- Revision (K102437)

Device Description:

"UNITED" U2 Total Knee System – PSA Type, Offset Stem Adapter is a modification of cleared Offset Stem Adapter (K082424). This device is manufactured from Ti-6Al-4V alloy (ASTM F136) and identical to the previously cleared offset stem adapter. The Offset Stem Adapter is intended for use in patients with inadequate bone stock. It allows the stem

extension to be positioned away from the center of femoral or tibial component, and to center the stem extension within the bone medullar canal.

There are three available offset sizes for the subjected device including 2, 4 and 6mm. It is able to be assembled with the femoral component, tibial baseplate and stem component utilizing Morse taper locking mechanism, and the Morse taper design is identical to our cleared Offset Stem Adapter (K082424). The modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Indications:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance.

Basis for Substantial Equivalence:

The intended use, raw material, design rationale and sterilization method of current submission device is substantially equivalent to legally marketed "UNITED" U2 Total Knee System – PSA Type (K082424), "BIOMET" VanguardTm 360 Revision Knee System (K093293) and "MEDACTA" GMK® Total Knee System- Revision (K102437).

Performance Data:

A fatigue strength test was conducted to evaluate the configuration strength of the Offset stem adapter, and the test result demonstrated that this device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

United Orthopedic Corporation
Attn: Fang-Yuan Ho
Regulatory Affairs Manager
Number 57, Park Avenue 2, Science Park
Hsinchu 300
TAIWAN

Re: K131116
Trade/Device Name: U2 Total Knee System – PSA Type, Offset Stem Adapter
Regulation Number: 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 30, 2013
Received: October 1, 2013

Dear Fang-Yuan Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin E. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K131116

Device Name: U2 Total Knee System- PSA Type, Offset Stem Adapter

Indications for Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices